epic S SERIES

# User Manual

*EPIC S-Series User Manual P/N 5400463-EU Rev. D*

BIOLASE®

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# INTRODUCTION

The EPIC™ *S-Series* diode laser is a surgical and therapeutic device at the cutting edge of technology, designed for a wide variety of surgical soft tissue procedures, as well as for use in providing temporary relief of minor pain.

The EPIC *S-Series* utilizes a solid state diode as a semiconductor source for invisible infrared radiation. The energy is delivered to the treatment site via flexible fiber connected at one end to the laser source and the other end to the handpiece. Various types of single use, disposable tips are designed and optimized for different surgical applications. The device is activated by means of a wireless footswitch.

This is a prescription device that is indicated for professional use only by licensed medical practitioners. The use of this device requires proper clinical and technical training. This manual provides instructions for those professionals that have completed the appropriate training.

When used and maintained properly, the EPIC *S-Series* will prove a valuable addition to your practice. Please contact your BIOLASE-authorized distributor for any service needs.

# 1.PACKAGING

## 1.1 SYSTEM PARTS LIST

The EPIC *S-Series* laser system includes the following:

1. Laser console (lithium ion battery pack already installed)
2. Screen Protectors (Peel-off clear screen cover - qty. 30)
3. Delivery System (installed)
4. Assorted Surgical Tips
5. Surgical Handpieces (2)

   Deep Tissue Handpiece (1) (shipped separately)
6. Three (3) pairs of protective laser eyewear (two (2) pairs of doctor safety glasses, one (1) pair of darker patient safety glasses)
7. DC power supply and power cord (1)
8. Welcome Kit (Welcome Letter, Product Registration Card, Limited Warranty Information, User Manual)
9. Laser Warning Sign
10. Tip Initiation Kit
11. Remote Interlock cable
12. Philips-head screwdriver (for installing Footswitch batteries)
13. Footswitch
14. AAA batteries (2)

**NOTE:** The laser ships with the lithium ion battery pack already installed.

**NOTE:** Use proper care when transporting the unit. Refer to Section 8 in this User Manual for instructions.

**WARNING:** No modification of this equipment is allowed.

## 1.2 FACILITY REQUIREMENTS

| | |
|---|---|
| Electrical Supply (100-240V ~): | 1.5A, 50/60Hz |
| Environmental Requirements: | Temperature: 20-25ºC<br>Humidity: 15-95%, Non-condensing |

# 2. EQUIPMENT DESCRIPTION

## 2.1 GENERAL

The EPIC S-Series system consists of three components:

- Laser console

- Delivery System

- Wireless Footswitch

## 2.2 LASER CONSOLE

The Console has a Display Panel (Touch Screen and Control Button) in front. It can be powered by an external mains power supply or an internal replaceable lithium ion battery pack, 14.4V, 2.9 Ah.

## 2.3 CONTROL PANEL

| ITEM | ITEM DESCRIPTION |
|---|---|
| CONTROL Button | Activates the controls and display; places the unit into STANDBY or READY mode. |
| LED Indicator | • *Amber* indicates unit is in STANDBY mode.<br>• *Green* indicates unit is in READY mode.<br>• Blinking *green* indicates the emission of laser power.<br>• Blinking *blue* indicates pairing between the footswitch and laser console is active |

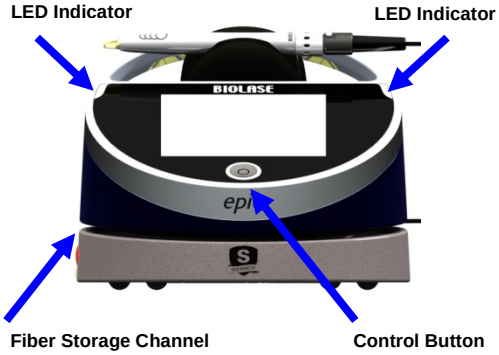



*Figure 2.1: Control Panel (Front View)*

## 2.4 SURGICAL DELIVERY SYSTEM

**NOTE:** All fiber optic cables, handpieces & tips are shipped non-sterile.

The EPIC S-Series Delivery System with Surgical Handpiece consists of:

- Re-useable Fiber Optic Assembly
- Re-useable Surgical Handpiece (Figures 2.9)
- Disposable Tips (Appendix A)

**NOTE:** The fiber optic cable is detachable from the console. The handpiece is a re-usable accessory and will require cleaning and sterilization prior to each patient treatment. Tips are intended for single-use only and must be disposed of after each patient use. Proper tip disposal in a biohazard medical waste Sharps container is required. Tips must be steam sterilized prior to use. For instructions on cleaning and sterilization of the handpiece and tips Refer to Section 8.

## 2.5 FIBER OPTIC CONNECTION

The EPIC S-Series ships with the fiber optic cable already attached.

**CAUTION:** Do not connect or disconnect the fiber while the laser console is turned on. Only connect or disconnect the fiber when the laser console is turned off.

To disconnect the fiber optic cable from the laser console, **make sure the laser console is turned off and the cable is completely unwound from the console base**, grab the fiber optic access plug and slowly pull it straight back from the optical access port (Figure 2.3).

To re-install the fiber optic cable, **make sure the laser console is turned off**. The fiber optic cable is attached to the console by inserting the optical access plug (Figure 2.2) into the optical access port (Figure 2.3).

**NOTE:** You should hear the fiber optic “click” into place; if you do not hear it “click,” remove the fiber optic and reinstall it.

For storage, wind the cable in the fiber storage channel around the base of the console in a counterclockwise direction (Figure 2.1).

**CAUTION:** Do not bend the fiber optic at a sharp angle, as it is can break. Make sure it is not caught or pinched between the housing and the fiber optic access plug.

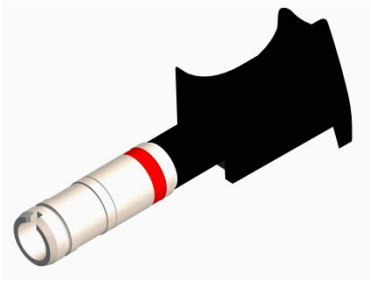


*Figure 2.2:* Fiber *Optic Access Plug*

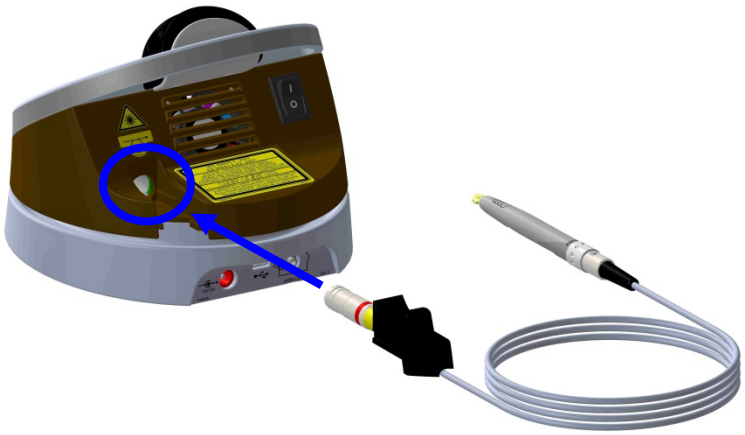


*Figure 2.3: Optical Access Port*

## *2.6 SINGLE-USE TIPS*

The tips are single-use accessories and are provided in three core diameters: 200µm, 300µm, and 400µm, in different lengths (see Appendix A).

| | |
|---|---|
| **CAUTION:** | **Tips are single-use only** to avoid cross-contamination and are designed to withstand only a single sterilization cycle; they must be disposed of after use in a biohazard medical waste Sharps container.<br><br>Always visually inspect the tip prior to use to make sure it is free of debris or damage. |

| | |
|---|---|
| **CAUTION:** | Be aware that the metal / plastic cannula on the tips may become hot during use. Avoid contact of the cannula with any tissue. |

To connect the tip, **first connect the handpiece to the fiber**, then insert the tip firmly into the distal end of the handpiece as far as it will go, and tighten by turning clockwise (Figure 2.4). Bend the metal cannula according to the specific procedure requirements (Figure 2.7).

Remove the fiber tip by twisting the tip counterclockwise (Figure 2.5).

| | |
|---|---|
| **NOTE:** | To provide proper laser operation, **do not** connect tips when the handpiece is disconnected from the fiber. |

*Tip Assembly*

*Figure 2.4: Insert the fiber tip into the handpiece **(only when the handpiece is connected to the fiber)** and twist **clockwise** until snug*

*Figure 2.5: Remove the fiber Tip by twisting the tip **counterclockwise***

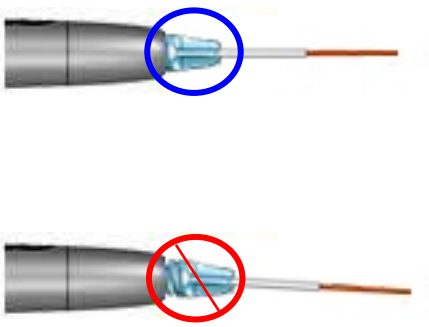


*Figure 2.6: When installing the tip, make sure it is seated properly (thread correctly)*

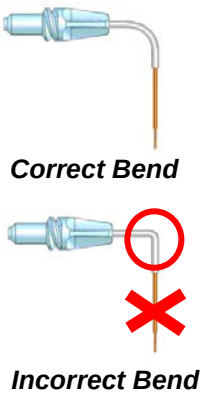



*Figure 2.7: Bending the tip cannula*

**WARNING:**

When the aiming beam is not present or has a significantly asymmetrical shape:

►For tips that require initiation: change the tip

►For tips that do not require initiation: change the tip; press ✔ to bypass initiation requirement.

## 2.7 SURGICAL HANDPIECE ASSEMBLY

► Connect the handpiece to the fiber optic assembly by pushing the handpiece on the fiber shaft until it clicks on and is secured at connected position (Figures 2.8, 2.9).

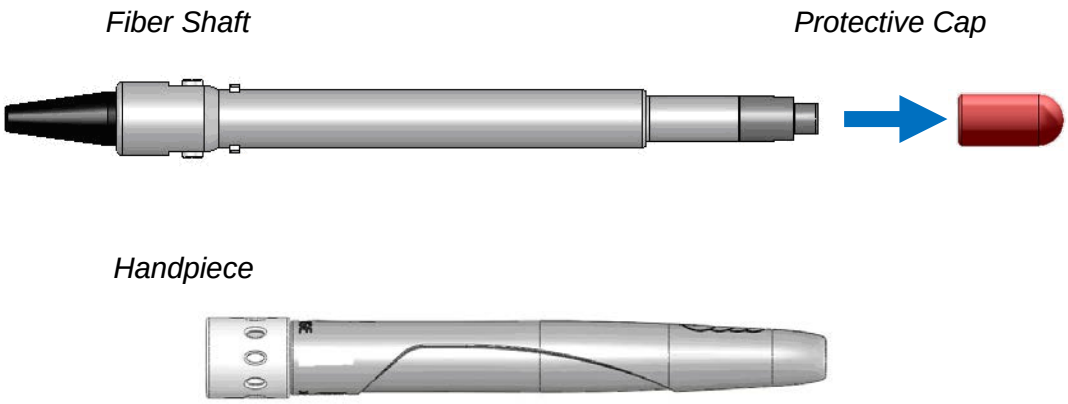



*Figure 2.8: Connecting the handpiece to the fiber optic assembly*

*Figure 2.9: Surgical handpiece Assembly fully assembled*

► Disconnect the handpiece from the fiber optic assembly (Figure 2.10) by

1. Taking the handpiece body in one hand and the shaft in the other,
2. Pushing the two buttons on the Fiber Shaft,
3. Pulling the handpiece with the ring to separate.

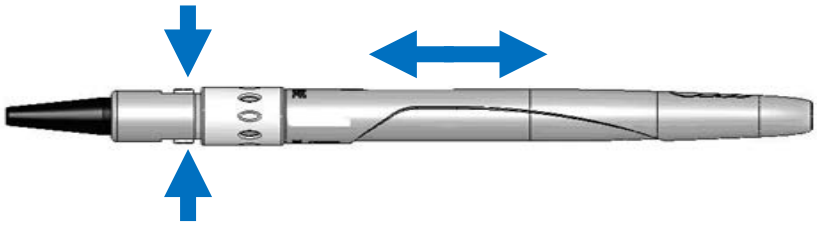


Figure 2.10: *Disconnect the handpiece from the fiber optic assembly by pressing both buttons at the base of the Fiber Shaft*

## *2.8 DEEP TISSUE HANDPIECE*

| | |
|---|---|
| **NOTE:** | The Deep Tissue Handpiece is reusable and equipped with a disposable non-sterile protective shield for single patient use. The handpiece is non-sterile and requires disinfection before and after each patient treatment. **This handpiece cannot be sterilized in the autoclave.** For instructions on cleaning the handpiece, refer to section 8.<br><br>Always wipe the disposable shield with alcohol prior to use. The disposable shield is for single-use only to avoid cross-contamination. Dispose of when treatment session is completed. |

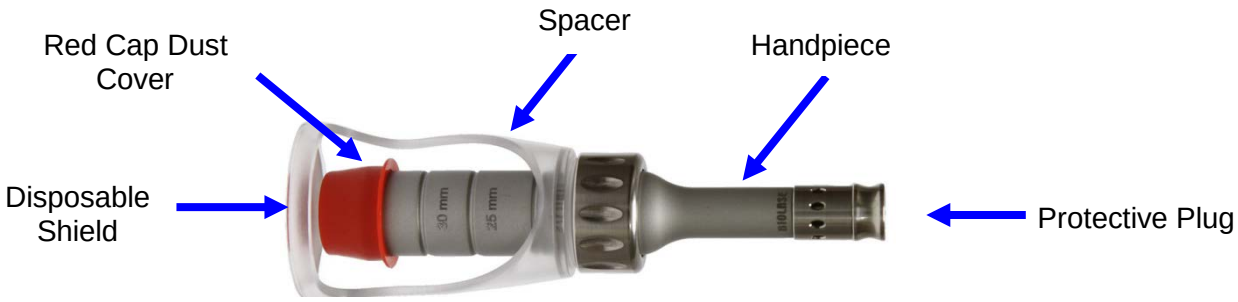



*Figure 2.11: Deep Tissue Handpiece*

- Remove Red Cap Dust Cover and protective plug from the Deep Tissue Handpiece.
- Slide the handpiece over the shaft until it clicks into place (Figure 2.12).

*Figure 2.12*

- Place the protective shield over the adjustable spacer (Figure 2.13).

*Figure 2.13*

- Loosen the Lock Ring and set the Spacer at the desired spot size Detent Location (Figure 2.14). Tighten the Lock Ring.

*Figure 2.14*

The handpiece is now ready to use.

To remove the handpiece, press and hold the buttons on the side of the fiber shaft and pull the handpiece away from the shaft.

# 3. SAFETY

## 3.1 PRECAUTIONS

Failure to comply with precautions and warnings described in this User Manual may lead to exposure to dangerous optical radiation sources. Please comply with all safety instructions and warnings.

## 3.2 SAFETY INSTRUCTIONS

Follow these safety instructions before and during treatments:

- When the laser is in use, all operatory entrances must be marked with an appropriate warning sign (one (1) included).

- Do not operate in the presence of explosive or flammable materials. Flammable anesthetics or oxidizing gases such as nitrous oxide ($N_2O$) and oxygen should be avoided. Solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before laser is used. Attention should also be drawn to the danger of ignition of endogenous gases.
- All persons present in the operatory must wear protective laser eyewear.

**NOTE:** For replacement or additional protective laser eyewear, please contact BIOLASE.

**CAUTION:** Periodically inspect laser eyewear for pitting and cracking.

**LASER WARNING:** Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

**WARNING:** Do not use this unit if you suspect it of functioning improperly or other than described herein.

**CAUTION:** This unit has been designed and tested to meet the requirements of electromagnetic, electrostatic, and radio frequency interference standards. However, the possibility of electromagnetic or other interference may still exist. Relocating the device may help to eliminate the interference.

**CAUTION:** Always ensure that the proper laser parameters are set before the EPIC S-Series laser is used in a clinical setting.

**LASER WARNING:** Always ensure that the protective laser eyewear is appropriate for the laser wavelength.

- Do not look directly into the beam or at specular reflections.
- Never direct or point the beam at a person's eyes.
- Always place the system into STANDBY mode (by pressing the Control Button while in READY mode) before exchanging handpieces or disposable tips.
- Toggle the ON/OFF switch (located on the rear of the console) to the OFF (O) position before leaving unit unattended.

**LASER WARNING:** Do not open unit housing at any time. Danger from optical radiation may exist.

**LASER WARNING:** Do not aim the laser at metallic or reflective surfaces, such as surgical instruments or dental mirrors. If aimed directly at these surfaces the laser beam will reflect and create a potential hazard.

## *3.3 SAFETY FEATURES*

### *Energy Monitor*

The energy monitor measures and verifies power output. Power deviations of more than ± 20% from the selected value will cause the display to show the error message: "LASER CURRENT HIGH/LOW".

The laser console will not operate until the system first clears the error and then goes into READY mode. If the error message persists, please contact BIOLASE Service at 1-800-321-6717.

### *System Monitor*

The system monitors the emergency stop switch, remote key, wireless footswitch connection, and output power. An error in any one of these will stop the system. The text display will indicate the type of error. Operation will not resume until the error is cleared.

## *Power Switch*

The laser console can be switched ON (I) or OFF (O) using the Power Switch on the back of the console.

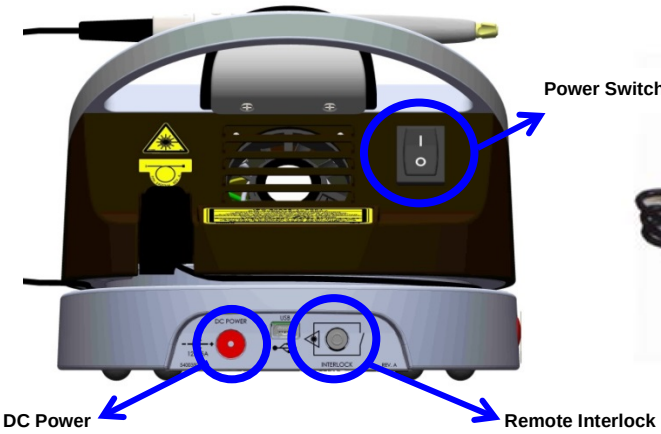



*Figure 3.1: Power Switch, DC Power Input, Remote Interlock*

*Figure 3.2: Power Supply Module with cord*

| | |
|---|---|
| **CAUTION:** | Use only the Power Supply Module supplied with the EPIC S-Series laser system (BIOLASE Part Number 2400129). |

## *Access Key Code*

The Access Key Code prevents unauthorized use of the system. It is activated every time system is turned on with the Power Switch (refer to Section 4 for code).

| | |
|---|---|
| **NOTE:** | Placing the laser in sleep mode by pressing and holding the Control button on the front panel does not re-set the Access Key Code. Turn the Power Switch OFF (O) only when the system will not be in use for a long period of time. |

## *Control Button*

Once the power switch is set to the ON (I) position, enter the access key code. After setting the desired parameters for a procedure, press the CONTROL button on the control panel to enter into READY mode. The aiming beam will illuminate to indicate that the system is ready for use.

## *Wireless Footswitch*

The EPIC S-Series will not emit laser energy until the user presses down on the footswitch while the laser is in READY mode. The footswitch is designed to work using wireless technology.

Two (2) AAA batteries are required to power the footswitch (included). For instructions on how to replace the footswitch batteries, see Section 8.

The footswitch is protected by a metal cover. To access, first press down on the cover to unlatch it. Now the footswitch can be pressed to fire the laser.

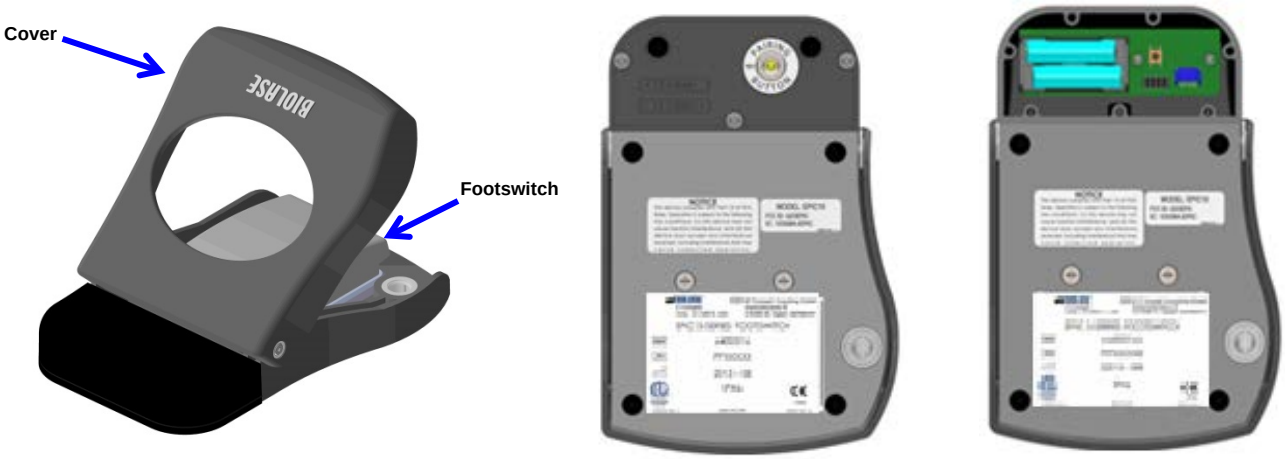



*Figure 3.3: Footswitch Assembly*

## *Remote Interlock*

This feature allows the laser console to be connected to the remote sensor, preventing its operation when triggered (*e.g.*, by opening door). The electric cable from this connector should be wired to the normally closed switch, sensing the opening of a door and turning the laser console off when the switch is open.

To override this feature, don't connect the plug.

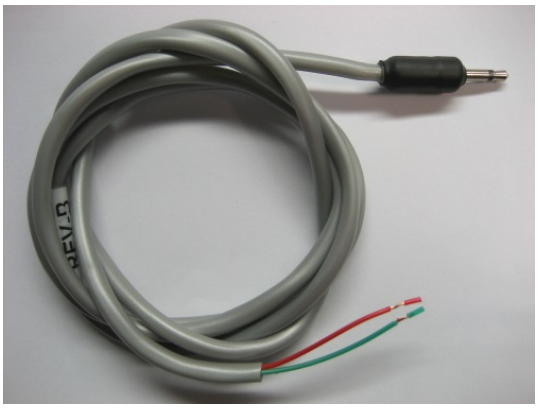


*Figure 3.4: Remote Interlock Connector*

### *Emergency Stop*

Press the red Emergency Laser Stop button to instantly turn off the laser console. The error screen will display an “Emergency Switch Error” message and the amber LED will begin flashing. To clear the error, press the Emergency Laser Stop button again; in 2 to 5 seconds the amber LED will stop flashing and the system will automatically go into STANDBY mode.

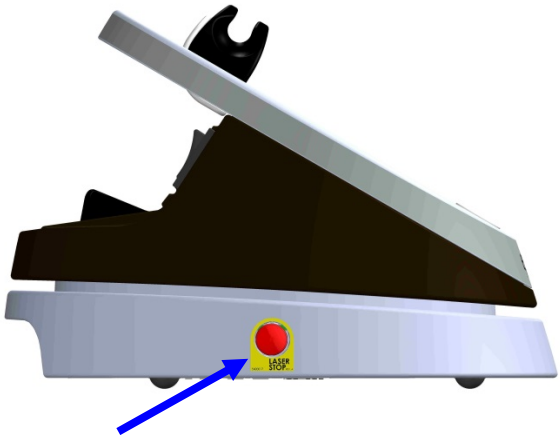


*Figure 3.5: Emergency Laser Stop (Left Profile View)*

### *Functional Display*

The System Color Display with Touch Screen and LED indicators on the control panel show the functional conditions of the system.

## *3.4 SAFETY CLASSIFICATION*

The following safety classifications are applicable to the device:

- Laser Radiation – Class 4
- Aiming Beam – Class 2
- Type of protections against electrical shock – Class 2
- Degree of protection against electrical shock – Type B Applied Part
- Not protected against water ingress – Ordinary Equipment
- Not suitable for use in presence of flammable anesthetic mixture
- Operation Mode – Continuous Wave and Pulse Mode
- Wireless Footswitch – IPX6

# 4. OPERATION INSTRUCTIONS

## 4.1 SYSTEM SETUP

- Place the unit in a clean, dry, and well-ventilated area.
- Verify power switch is in the OFF (O) position.
- EPIC S-Series will work using either DC power or the rechargeable battery pack:
  - *DC Power*: Connect the power cord of the power supply to the laser console and plug into a wall outlet
  - *Rechargeable Battery*: The EPIC S-Series is shipped with the battery pack already installed; to charge the battery pack, connect the power cord of the DC power supply to the laser console and plug into a wall outlet. Before first use, fully charge the battery (at least 3 hours). Once the battery is charged, unplug the power cord from the wall outlet and the laser console. The laser console will run on battery power alone.

| | |
|---|---|
| **NOTE:** | The system ships from the factory with the fiber already connected to the laser console |

| | |
|---|---|
| **NOTE:** | To fully charge the battery, plug the power supply in and then turn the laser console ON (I) at the Power Switch. The laser console will start to charge and the unit will go into sleep mode (with the screen off) after 5 minutes; if the power supply is plugged in but turned OFF (O) at the Power Switch, the battery will still charge, but at a slower rate. |

| | |
|---|---|
| **CAUTION:** | Do not connect or disconnect the fiber while the laser console is turned on. Only connect or disconnect the fiber when the laser console is turned off. |

| | |
|---|---|
| **CAUTION:** | Do not cover or block ventilation channels. These channels provide an air-flow path to cool the unit. |

| | |
|---|---|
| **CAUTION:** | Do not bend the fiber optic at a sharp angle, as it is can break. Make sure it is not caught or pinched between the housing and the fiber optic access plug. |

- Remove protective cap from the end of the fiber shaft (see Figure 2.8).
- Carefully connect the handpiece to the fiber optic assembly (see Figure 2.9).
- Insert the selected tip and tighten it clockwise until snug (see Figure 2.4).
- Wind any excess fiber optic cable onto the fiber spool counterclockwise in the fiber storage channel around the base of the console (see Figure 2.1).
-

The handpiece is now ready to use. To store the handpiece, place it in the handpiece holder located at the top of the laser console .

**LASER WARNING:** Never point the laser at a person's eyes.

**LASER WARNING:** Never operate the laser without a handpiece or fiber tip attached.

**LASER WARNING:** All persons present in the operatory must wear protective eyewear when the laser is in use.

## 4.2 OPERATION - TURN ON THE EPIC S-SERIES LASER

- Ensure that the battery has enough charge for operation, or connect the power supply cord to the power connector on the laser console and plug the cord into a wall outlet.
- Turn the Power Switch at the rear of the console to the ON (I) position. The "BIOLASE" logo screen will appear (Figure 4.1). After three (3) seconds the EPIC S-Series "Welcome" screen will be displayed (Figure 4.2).

*Figure 4.1*

*Figure 4.2*

*Figure 4.3*

- Enter the three digit access code using the touch screen. The Access Key Code is **888**. (If the incorrect code is entered, an '**X**' appears briefly in the window (Figure 4.3); press the '**X**' or wait 3 seconds to revert back to the Welcome screen; re-enter the correct code.
- The system will go to the HOME screen which identifies two procedure categories to choose from: Surgical, or Pain Therapy.

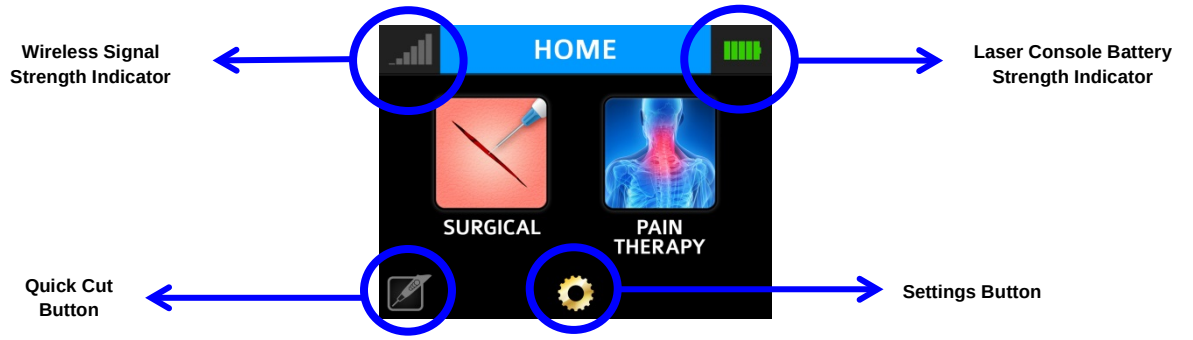
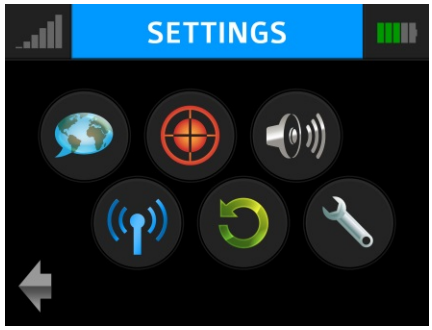



*Figure 4.4: Home Screen*

## 4.3 SETTINGS SCREEN

Pressing the Settings button on the HOME screen accesses the Settings screen; this screen allows the user to make changes to several system settings:




- Language Selection
- Aiming Beam (5 levels of brightness adjustment)
- Volume (5 levels of sound adjustment)
- Service Mode (accessible only by authorized BIOLASE Service Representatives)
- Restore to Factory Default Settings
- Wireless Menu - Access to Pairing Screens

*Figure 4.5*

## 4.4 PAIRING THE FOOTSWITCH TO THE LASER CONSOLE

Verify that the footswitch and laser console are paired; a blue LED indicator light on the laser console will blink when pairing is established. The laser and footswitch are shipped already paired. However, if pairing is not confirmed, an "" will appear in the pairing icon located in the upper left hand corner of the touchscreen (Figure 4.6).

*Figure 4.6*

To re-establish pairing, take the following steps:

1. Go to the Settings menu on the laser console display by pressing the Settings button and select the “Wireless” icon .

2. A screen will appear indicating that pairing of the footswitch to the laser console has been lost (Figure 4.7); press the green PAIR button. PAIR

*Figure 4.7*

3. The message that “PAIRING WILL NOW BEGIN” will appear; press the green check mark to continue (Figure 4.8).

*Figure 4.8*

4. To complete the pairing process, turn the footswitch over and press the Pairing Button for four (4) seconds (Figure 4.9).

*Figure 4.9*

5a. The Wireless screen will appear indicating that pairing was successful and that the footswitch and laser console are now paired (Figure 4.10).

Proceed to step 6.

*Figure 4.10*

5b. If pairing has not occurred, the Wireless screen will appear again indicating that pairing was not successful (Figure 4.11); press the green button to repeat steps 3 – 5a.

*Figure 4.11*

6. Press the Settings button to return to the Settings menu; press the arrow on the bottom left of the Settings screen to return to the Home screen (Figure 4.12).

*Figure 4.12*

## *4.5 CONTROL BUTTON*

The CONTROL button on the front of the laser console is a multi-functional button (Figure 2.1). Pressing and holding the Control Button for approximately two (2) seconds will allow the transition from STANDBY or READY mode to SLEEP mode. Note that you will not be allowed to go into READY mode unless you have chosen a treatment module on the HOME screen first.

## *4.6 ENTERING READY OR STANDBY MODES*

Press and release the Control Button to place the laser console into either READY or STANDBY mode. The laser console will only emit laser energy when the footswitch is pressed and the laser console is set to READY mode. While in READY or STANDBY mode, mode setting and/or power setting values may be changed only when the laser is not firing. If the

laser is firing (*i.e.*, the footswitch is engaged), the ability to change the settings is blocked. ("READY" or "STANDBY" is displayed in the lower right hand corner of the display screen).

## 4.7 READY MODE

When entering READY mode, the laser console fan will turn on and pressing the footswitch will activate laser radiation. There is a two (2) sec delay between switching to READY mode and the ability of the laser console to emit a laser beam.

| | |
|---|---|
| **NOTE:** | The aiming beam is on only when the laser is in READY mode or when adjusting the brightness of the beam while in Settings mode. If the aiming beam is not visible in either instance, remove the handpiece and confirm the beam is actually on by shining the end of the trunk fiber on a plain, non-reflective surface. **DO NOT** look directly at the output end of the trunk fiber. If the aiming beam is not on, turn off the laser console, then remove and re-install the trunk fiber (see Section 2.6). If the aiming beam is still not on, turn off the laser console and call Biolase Service. |

## 4.8 WIRELESS FOOTSWITCH

The wireless footswitch is powered by two (2) AAA batteries.

When the wireless footswitch is pressed in READY mode and the laser fires, a beeping sound indicates that laser energy is present. A green LED will begin flashing and a blue LED will light at the top corners of the laser console, confirming the footswitch and laser are paired.

In the top left corner of most screens is a Signal Strength Indicator which displays the signal strength between the laser console and the footswitch (strongest is five (5) bars). Pressing and releasing the footswitch while in Standby mode will update this indicator. Although the unit will work with a signal level as low as one (1) bar, a weaker signal level will make the connection between the footswitch and laser console more vulnerable to wireless (RF) interference from other sources, such as cell phones or microwaves. To improve the signal strength, reposition either the footswitch or the laser console until the signal indicator achieves the strongest possible level for optimal operation.

| | |
|---|---|
| **NOTE:** | When the footswitch is not in use, it will go into SLEEP mode to conserve battery power. It automatically reactivates when it is pressed. |

## 4.9 PEAK POWER DISPLAY

This number is shown only when the system is in pulse mode and presents the value of the peak power based on the Power Setting and Pulse Mode.

## 4.10 PULSE MODE SELECTION

Pulse Mode selection graphically indicates whether the system is in Continuous (CW) mode or in Pulse mode.

In Continuous mode, laser power is constantly delivered when the laser console is in Ready mode and the wireless footswitch is activated.

In Pulse mode, laser power is delivered in repetitive pulses, controlled by the Pulse Length and Pulse Interval settings. Pressing the Pulse Mode button will allow switching between Pulsed and Continuous modes (Figure 4.14).

| MODE* | PULSE DURATION (on) | PULSE INTERVAL (off) | Duty Cycle (Time On / Time off) |
|---|---|---|---|
| CP0 | 10 microseconds | 40 microseconds | 20% |
| CP1 | 100 microseconds | 200 microseconds | 33% |
| CP2 | 1 millisecond | 1 millisecond | 50% |
| P3 | 20 milliseconds | 20 milliseconds | 50% |

**CP = Comfort Pulse; P3 = Pulsed Mode which is the standard for most diode lasers currently available to the marketplace*

*Figure 4.13*

**NOTE:** Operating the laser at a shorter pulse duration typically results in lower tissue temperature.

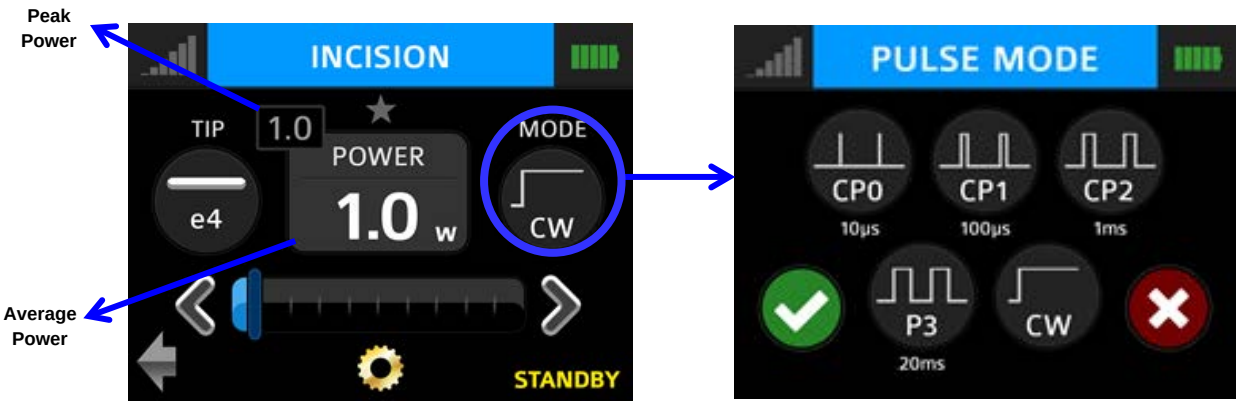



*Figure 4.14*

## 4.11 USING THE EPIC S-SERIES TOUCH SCREEN DISPLAY

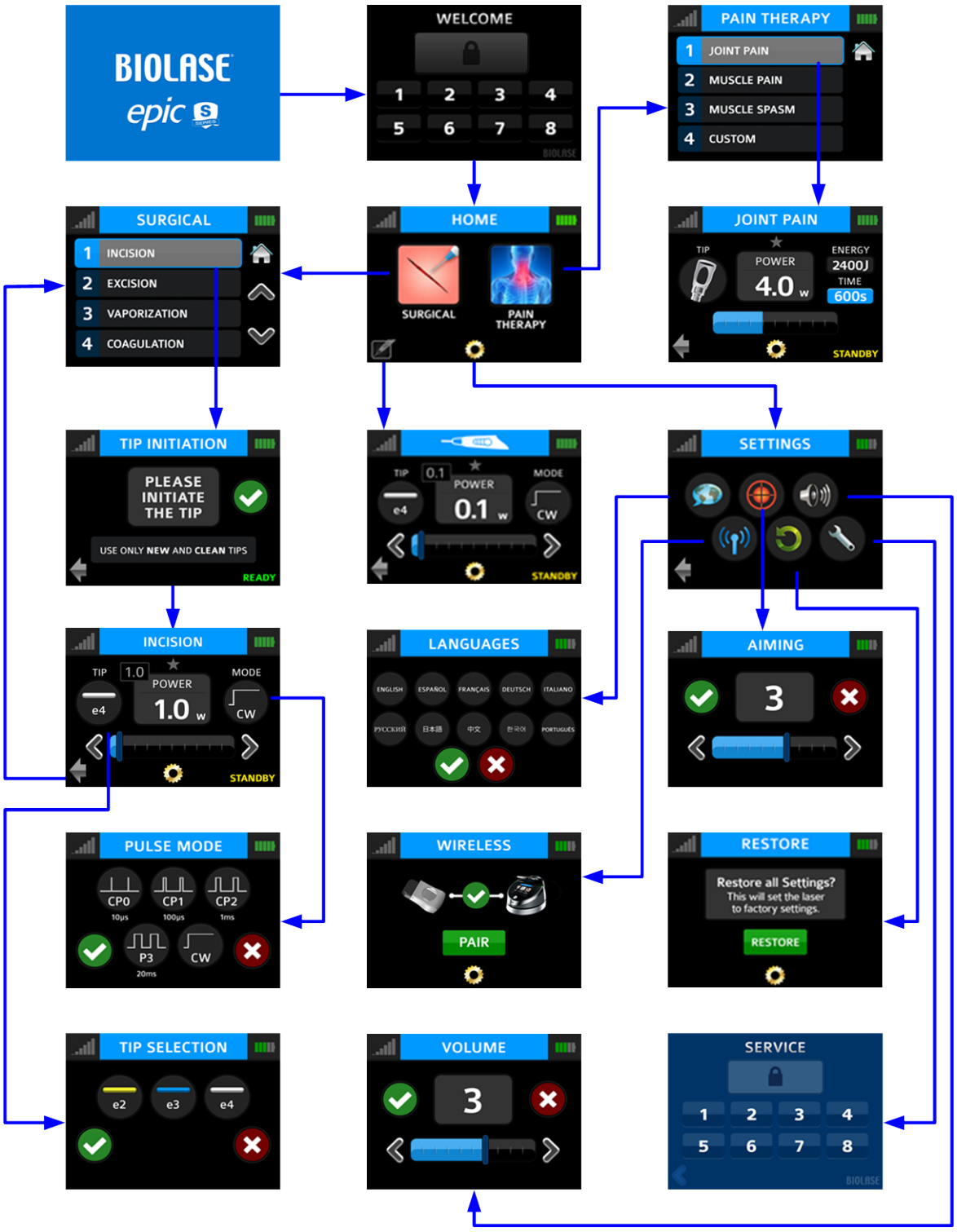



*Figure 4.15*

## 4.12 SURGICAL PROCEDURES SELECTION SCREEN

The EPIC S-Series has the ability to store up to 13 pre-set procedures. For Surgical, EPIC S-Series is factory-installed with 4 pre-programmed procedural presets and 4 slots for custom pre-sets, plus the Quick Cut option; for Pain, there are 3 pre-programmed presets with 1 slot for custom pre-sets. However, all of the pre-sets can be customized to your preference.

In order to customize the operating parameters (e.g., power, pulse duration, interval, etc.) for a particular clinical procedure:

1. Select SURGICAL on the HOME screen to access the surgical pre-set selection screen; scroll to the pre-set you wish to overwrite (Figure 4.16).

2. Press and hold the selected procedure for two (2) seconds. The parameters for that procedure will be changed and saved (the laser console will beep when the adjusted settings are saved).

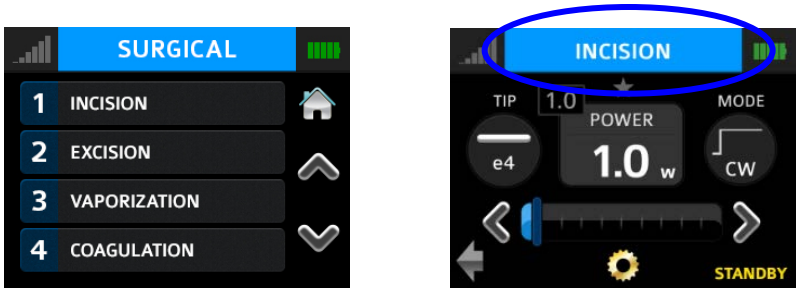



*Figure 4.16*

## 4.13 QUICK CUT BUTTON

The Quick Cut button located on the bottom left of the HOME screen (Figure 4.17) allows the user to bypass the Surgical Procedures Selection and Tip Initiation screens. When pressed, it goes directly to the Quick Cut screen. The user may use the preset settings displayed or customize them before proceeding with the procedure.

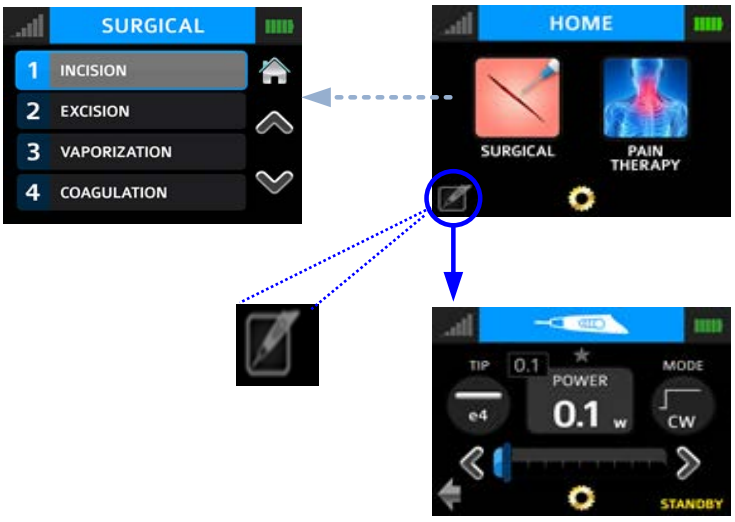



*Figure 4.17*

## 4.14 TURN THE LASER CONSOLE OFF

- Wind the fiber cable onto the fiber spool counterclockwise around the base of the console.
- Place the handpiece onto the handpiece holder.


| | |
|---|---|
| **CAUTION:** | Verify that the fiber optic tubing assembly is not twisted once the handpiece is returned to the holder. The fiber may break if it is twisted. |

- Press the CONTROL button on the front of the console for more than 2 seconds to turn the display off.
- Press the Power Switch at the rear of the laser console to the OFF (O) position if the laser system will not be used for a long period of time.

# 5. SPECIFICATIONS

## 5.1 GENERAL

| | |
|---|---|
| Dimension | 5.7 in (W) x 4.4 in (H) x 6.5 in (L)<br>(14.5 cm x 11.2 cm x 16.5 cm) |
| Weight | 2.75 lbs / 1.25 kg |

## 5.2 ELECTRICAL

| | |
|---|---|
| Operating Voltage | 100V - 240V ~ at 1.5A |
| Frequency | 50/60Hz |
| External Fuses | None |
| Main Control | Power Switch |
| Remote Interruption | Remote Interlock |
| Disable Control | Emergency Stop Button |
| Battery | Lithium Ion Rechargeable, 14.4V, 2.9Ah |
| DC Power Supply Module | 12V DC, 5A |

## 5.3 LASER

| | |
|---|---|
| Laser Classification | IV (4) |
| Medium | InGaAsP Semiconductor diode |
| Wavelength | 940 ± 10nm |
| Max Power Output | 10W |
| Power Accuracy | ± 20% |
| Power Modes | Continuous, Pulse Modulation |
| Fiber Tips Diameter | 200µm, 300µm, 400µm |
| Pulse Duration | 0.01ms – 20ms |

| | |
|---|---|
| Pulse Interval | 0.04ms – 20ms |
| Pulse Repetition Rate | Up to 20kHz (for reference) |
| Spot size | |
| Surgical Handpiece | 400µm (maximum in contact mode) |
| Deep Tissue Handpiece | 30mm diameter = 7.1cm$^2$ area |
| NOHD | 4.77 meters |
| Beam Divergence | 8 - 22° per side angle |
| Standard Fiber Cable Length | 6.8 feet (2 meters) |

## *5.4 OTHER LIGHT SOURCES*

| | |
|---|---|
| Aiming Beam | Laser diode, max 1mW, 625nm – 670nm, Class 2 |

# 6. CONTRAINDICATIONS, WARNINGS & PRECAUTIONS

## 6.1 CONTRAINDICATIONS

All clinical procedures performed with EPIC S-Series must be subjected to the same clinical judgment and care used with traditional techniques. Patient risk must always be considered and fully understood before clinical treatment. The clinician must completely understand the patient's medical history prior to treatment. Exercise caution for general medical conditions that might contraindicate a local procedure. Such conditions may include allergy to local or topical anesthetics, heart disease (including pacemakers), lung disease, bleeding disorders, sleep apnea or an immune system deficiency, or any medical conditions or medications that may contraindicate use of certain light/laser type sources associated with this device. Medical clearance from patient's physician is advisable when doubt exists regarding treatment.

## 6.2 WARNINGS AND PRECAUTIONS

### *Eyewear*

Doctor, patient, assistant and all others inside the operatory must wear appropriate laser eyewear protection for the diode laser wavelength of 940 ± 10nm.

### *Anesthesia*

In soft tissue cases anesthesia may not be required, but patients should be closely monitored for signs of pain or discomfort at all times. If such signs are present, adjust settings, apply anesthesia or cease treatment if required.

### *Adjacent Structures*

EPIC S-Series is designed to remove soft tissues. Therefore, always be aware of adjacent structures and substructures during use. Be extremely careful not to inadvertently penetrate or ablate underlying or adjacent tissues. Do not direct energy toward hard tissue such as bone. Do not direct energy towards any metallic surfaces or non-soft tissue surfaces. Exercise extreme caution when using this where critical structures (i.e. nerves, vessels) could be damaged. Do not proceed with using the laser if visibility is limited in these areas.

### *Suction*

Use high-speed suction as required to maintain a clear field of vision during treatment. Do not use the EPIC S-Series if you cannot clearly see the treatment site.

## *Plume Removal*

Special care must be taken to prevent infection from the laser plume generated by vaporization of virally or bacterially infected tissue. Ensure that appropriate protective equipment (including high-speed suction to remove the plume, appropriately filtered masks, and other protective equipment) is used at all times during the laser procedure.

## *Clinical Use*

Use your clinical judgment to determine all aspects of treatment including, but not limited to, the laser treatment protocol, technique, power settings, pulse duration and interval settings, mode of operation as well as the accessories (e.g. tip type) and other procedural requirements. Closely observe and monitor clinical effects and use your judgment to determine clinical parameters and approach for the treatment. Make appropriate power, pulse length, and interval adjustments to compensate for varying tissue compositions, density, and thickness. Always start treatment at the lowest power setting for that specific indication and increase as required. BIOLASE assumes no responsibility for parameters, techniques, methods or results.

## *Training*

Only licensed professionals who have reviewed and understood this User Manual should use this device. BIOLASE assumes no responsibility for parameters, techniques, methods, or results. Physicians must use their own clinical judgment and professionalism in determining all aspects of treatment, technique, proper power settings, interval, duration, etc.

**LASER WARNING:** Never point the laser at a person's eyes. All persons present in the operatory must wear protective eyewear when the laser is in operation

# 7. CLINICAL APPLICATIONS

## 7.1 INTRODUCTION

To efficiently remove tissues it is imperative to understand the nature of the EPIC S-Series device. Please review this section carefully, practice on model tissues, and attend a diode laser training session before using this device in a clinical situation.

## 7.2 INDICATIONS FOR USE

The EPIC S-Series is intended for use as a laser surgical instrument for use in general surgery, plastic surgery, and dermatology procedures as noted in Figure 7.1.

*Ear, Nose and Throat and Oral Surgery:*
Hemostasis, incision, excision, ablation, and vaporization of tissues from the ear, nose, throat and adjacent areas, including soft tissue in the oral cavity, such as:

- Removal of benign lesions from ear, nose and throat
- Excision and vaporization of vocal cord nodules and polyps
- Incision and excision of carcinoma in-situ
- Ablation and vaporization of hyperkeratosis
- Laryngeal papillectomy
- Excision and vaporization of herpes simplex I and II
- Neck dissection

*Arthroscopy:*
Hemostasis, incision, excision, vaporization, and ablation of joint tissues during arthroscopic surgery, such as:

- Meniscectomy
- Syovectomy
- Chondromalacia

*Gastroenterology:*
Hemostasis, incision, excision, and vaporization of tissue in the upper and lower gastrointestinal tracts via endoscopy, such as:

- Hemostasis of upper and lower GI bleeding
- Excision and vaporization of colorectal carcinoma
- Excision of polyps
- Hemostasis of colonoscopy
- Hemostasis of esophageal varices

*Orthopedics*

- Dissect and coagulate

*General Surgery, Dematology & Plastic Surgery, and Podiatry:*
Excision, ablation, vaporization, and photocoagulation of skin lesions, hemostasis, incision, excision, vaporization, ablation, and debulking of soft tissue, abdominal, rectal, skin, fat or muscle tissue, and dermabrasion, such as:

- Matrixectomy
- Excision of neuromas
- Excision of periungual and subungual warts
- Excision of plantar warts
- Excision of Keloids
- Excision of cutaneous lesions
- Hemorrhoidectomy
- Hepatobiliary
- Mastectomy
- Appendectomy
- Debridement of decubitus ulcer
- Dermabrasion
- Vaporization & hemostasis of capillary hemangioma
- Excision, vaporization & hemostasis of abdominal tumors
- Excision, vaporization & hemostasis of rectal pathology
- Pilonidal cystectomy
- Herniorraphy
- Adhesiolysis
- Parathyroidectomy
- Laparoscopic cholecystecomy
- Thyroidectomy
- Resection of organs
- *GI/GU:*
  Excision, vaporization, and hemostasis of abdominal and rectal tissues, such as:
- Hemorrhoidectomy
- Excision, vaporization, and hemostasis of rectal pathology
- Excision, vaporization, and hemostasis of abdominal tumors

*Gynecology:*
Ablation, excision, hemostasis, and vaporization of tissue, such as:

- Excision or vaporization of condylomata acuminata
- Vaporization of CIN (cervical intraepithelial neoplasia)
- Cervical conization
- Menorrhagia
- Ovarian cystectomy

*Neurosurgery:*
Vaporization, coagulation, excision, incision, ablation and hemostasis of tissue, such as:

- Hemostasis in conjunction with meningiomas
- Percutaneous Disc Decompression (PLDD)

*Ophthalmology:*

- Dacryocystorhinostomy transcanalicular
- Open DCR
- Tumor Excision
- Blepharoplasty

*Pulmonary Surgery:*
Hemostasis, vaporization, and excision of tissue, such as:

- Tracheobronchial malignancy or stricture
- Benign and malignant pulmonary obstruction

*Cardiac Surgery:*

- Coagulation and hemostasis of cardiac tissue

*Thoracic Surgery:*

- Thoracotomy
- Pulmonary resection
- Hemostasis
- Pericardiectomy
- Adhesiolysis
- Coagulation of blebs and bullae

*Urology:*
Hemostasis, vaporization, incision, coagulation, ablation, and excision of tissues, such as:

- Vaporization of urethral tumors
- Release of urethral stricture
- Removal of bladder neck obstruction
- Excision and vaporization of condyloma
- Lesions of external genitalia
- Circumcision
- Vaporization of the prostate to treat benign prostate hyperplasia (BPH)

*Dermatology/Aesthetics:*

- Photocoagulation of vascular & dermatological lesions of the face and extremities
- Photocoagulation of telangiectasia, venulectasia of the legs and face
- Treatment of reticular veins and branch varicosities
- Pyrogenic granuloma, lymphangioma and lymphangiomatosis disease, angiofibromas
- Superficial benign vascular lesions including Telangiectasias, hemangioma, Port wine stains, angiokeratoma, and benign epidermal pigment lesions as lentigines, epidermal nevi, spider nevi.
- Dermatological surgery: Condyloma acuminate, warts, small non-malignant skin tumors, small semi-malignant tumors as basaliomas, Bowe and Kaposi sarcoma, warty leucoplasty and ulcers debridement.
- Seborrheic keratosis
- Mixoid cyst
- Papillary varix
- Acne treatment

*Vascular Surgery:*

- Photocoagulation of vascular & dermatological lesions of the face and extremities
- Photocoagulation of telangiectasia, veinulectasia of the legs and face
- Treatment of reticular veins and branch varicosities

*Pain:*
Topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, minor sprains and strains, and minor muscular back pain; the temporary increase in local blood circulation; the temporary relaxation of muscle.

*Podiatry:*
Temporary increase of clear nail in patients with onychomycosis (e.g., Dermatophytes, Trichophyton rubrum and T. mentagrophytes, and/or yeast Candida Albicans, etc.)

*Figure 7.1*

## *7.3 SOFT TISSUE SURGERY*

### *Tip Initiation: Parameters and Method (Not required if using pre-initiated tips)*

Most soft tissue surgical procedures require initiation of the fiber tip. **The TIP INITIATION screen will appear (in READY mode) if tip initiation is recommended** and the system will automatically go to the settings shown in Figure 7.2 based on the tip used; while in the TIP INITIATION screen, initiate the tip by following the steps outlined below.

| Tip Diameter (µm) | (Preset) Power (W) | Mode |
|---|---|---|
| 400 | 1.4 | CW |
| 300 | 1.4 | CW |
| 200 | Tip initiation not required when used for recommended procedures | |

*Figure 7.2*

- Touch the tip to the surface of the initiation block, without activating the laser (don't press down on the footswitch (Figure 7.3).

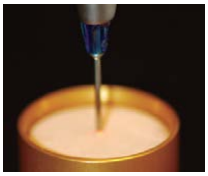


*Figure 7.3*

- Press the footswitch to activate the laser, allowing the tip to sink into the block. Pull the tip out when the metal cannula touches the block, still firing until just before the tip is out of the block (Figure 7.4).

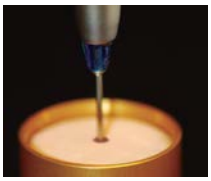


*Figure 7.4*

- Press the footswitch to activate the laser into the air once, you will see a white flash or the tip will glow (Figure 7.5).

*Figure 7.5*

- Repeat initiation process as needed to ensure the tip is initiated.

After tip initiation is completed, press the check mark to access the screen for the selected procedure (Figure 7.6).

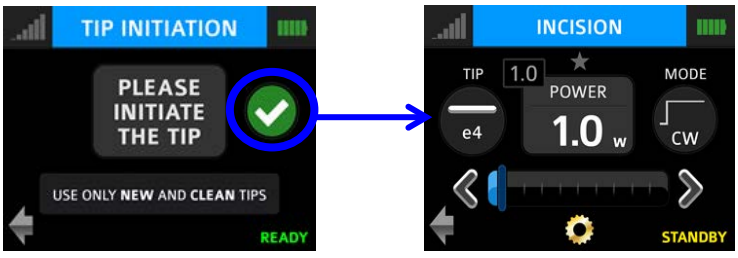



*Figure 7.6*

**CAUTION:** If the laser console is in READY mode, the laser will fire if the footswitch is activated.

## *7.4 TABLE OF SURGICAL SETTINGS*

Figure 7.7 represents the recommended initial clinical settings for each indication for use based on clinical case reports combined with in-vitro testing. During any of the following procedures you must observe the tissue under treatment closely and adjust the average power as needed to achieve optimum clinical outcomes with minimal collateral tissue damage.

**CAUTION:** Always use clinical judgment when selecting power, pulse length, and pulse interval parameters to ensure optimal clinical results. These recommended settings apply only to the 400µm tips.

**Fiber Tip Size (µm) = 400** **Pulse Interval = None** **CW = Continuous**

| Indication for Use | Power (W) | Total Energy (kJ) | Mode | Treatment Time (sec) | Handpiece | Spot Size $(mm)^2$ |
|---|---|---|---|---|---|---|
| Ablation and vaporization of kyperkeratosis | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Acne treatment | 1 | 127 | CW | 120 | Surgical | 0.126 |
| Adhesiolysis | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Angiokeratoma | 1.5 | 190.5 | CW | 120 | Surgical | 0.126 |
| Appendectomy | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Benign and malignant pulmonary obstruction | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Benign epidermal pigment lesions as lentigines | 1.5 | 190.5 | CW | 120 | Surgical | 0.126 |
| Blepharoplasty | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Bowe | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Cervical conization | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Chondromalacia | 1 | 127 | CW | 120 | Surgical | 0.126 |
| Circumcision | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Coagulation and hemostasis of cardiac tissue | 1.5 | 190.5 | CW | 120 | Surgical | 0.126 |
| Coagulation of blebs and bullae | 0.5 | 63.5 | CW | 120 | Surgical | 0.126 |
| Condyloma acuminate | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Dacryocystorhinostomy transcanalicular | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Debridement of decubitus ulcer | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Dermabrasion | 1.5 | 190.5 | CW | 120 | Surgical | 0.126 |
| Dermatological surgery | 2 | 254 | CW | 120 | Surgical | 0.126 |

| Indication for Use | Power (W) | Total Energy (kJ) | Mode | Treatment Time (sec) | Handpiece | Spot Size $(mm)^2$ |
|---|---|---|---|---|---|---|
| Dissect and coagulate | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Epidermal nevi | 1.5 | 190.5 | CW | 120 | Surgical | 0.126 |
| Excision and vaporization of colorectal carcinoma | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Excision and vaporization of condyloma | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Excision and vaporization of herpes simplex I and II | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Excision and vaporization of vocal cord nodules and polyps | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Excision of cutaneous lesions | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Excision of Keloids | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Excision of neuromas | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Excision of periungual and subungual warts | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Excision of plantar warts | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Excision of polyps | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Excision or vaporization of condylomata acuminata | 1.5 | 190.5 | CW | 120 | Surgical | 0.126 |
| Excision, vaporization & hemostasis of abdominal tumors | 1.5 | 190.5 | CW | 120 | Surgical | 0.126 |
| Excision, vaporization & hemostasis of rectal pathology | 1.5 | 190.5 | CW | 120 | Surgical | 0.126 |
| Hemangioma | 1.5 | 190.5 | CW | 120 | Surgical | 0.126 |
| Hemorrhoidectomy | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Hemostasis | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Hemostasis in conjunction with meningiomas | 1.5 | 190.5 | CW | 120 | Surgical | 0.126 |
| Hemostasis of colonoscopy | 1 | 127 | CW | 120 | Surgical | 0.126 |
| Hemostasis of esophageal varices | 1 | 127 | CW | 120 | Surgical | 0.126 |
| Hemostasis of upper and lower GI bleeding | 1 | 127 | CW | 120 | Surgical | 0.126 |
| Herniorraphy | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Incision and excision of carcinoma in-situ | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Kaposi sarcoma | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Laparoscopic cholecystecomy | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Laryngeal papillomectomy | 2 | 254 | CW | 120 | Surgical | 0.126 |

| Indication for Use | Power (W) | Total Energy (kJ) | Mode | Treatment Time (sec) | Handpiece | Spot Size $(mm)^2$ |
|---|---|---|---|---|---|---|
| Lesions of external genitalia | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Matrixectomy | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Menisectomy | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Mixoid cyst | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Myomectomy | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Neck dissection | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Open DCR | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Ovarian cystectomy | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Papillary varix | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Parathyroidectomy | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Percutaneous Disc Decompression (PLDD) | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Pericardiectomy | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Photocoagulation of telangiectasia, veinulectasia of the legs and face | 1.5 | 190.5 | CW | 120 | Surgical | 0.126 |
| Photocoagulation of vascular & dermatological lesions of the face and extremities | 1.5 | 190.5 | CW | 120 | Surgical | 0.126 |
| Pilonidal cystectomy | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Port wine stains | 1.5 | 190.5 | CW | 120 | Surgical | 0.126 |
| Pulmonary resection | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Pyrogenic granuloma, lymphangioma and lymphangiomatosis disease, angiofibromas | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Release of urethral stricture | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Removal of benign lesions from ear, nose and throat | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Removal of bladder neck obstruction | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Resection of organs | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Seborrheic keratosis | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Small non-malignant skin tumors | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Small semi-malignant tumors as basalomas | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Spider nevi | 1.5 | 190.5 | CW | 120 | Surgical | 0.126 |
| Syovectomy | 2 | 254 | CW | 120 | Surgical | 0.126 |

| Indication for Use | Power (W) | Total Energy (kJ) | Mode | Treatment Time (sec) | Handpiece | Spot Size (mm)² |
|---|---|---|---|---|---|---|
| Telangiectasias | 1.5 | 190.5 | CW | 120 | Surgical | 0.126 |
| Thoracotomy | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Thyroidectomy | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Tracheobronchial malignancy or stricture | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Treatment of reticular veins and branch varicosities | 1.5 | 190.5 | CW | 120 | Surgical | 0.126 |
| Tumor Excision | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Ulcers debridement | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Vaporization & hemostasis of capillary hemangioma | 1.5 | 190.5 | CW | 120 | Surgical | 0.126 |
| Vaporization of CIN (cervical intraepithelial neoplasia) | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Vaporization of the prostate to treat benign prostate hyperplasia (BPH) | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Vaporization of urethral tumors | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Warts | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Warty leucoplasty | 2 | 254 | CW | 120 | Surgical | 0.126 |
| Temporary increase of clear nail in patients with onychomycosis | 7.5 | 254 | CW | 30 ON/ 30 OFF/ 30 ON | Deep Tissue | 30 |

*Figure 7.7*

## *Pre-programmed Surgical Settings*

**NOTE:** The following initial clinical settings are based on clinical case reports combined with in-vitro testing; however, they are not universal. Always use your clinical judgment when selecting power, pulse length, and pulse interval parameters to ensure optimal clinical results.

To access the pre-programmed procedure values:

1. Go to the Procedures menu by pressing the Surgical icon on the Home screen.
2. Press the button associated with the desired procedure.

To store your personal preferred settings for any procedure:

A. Follow steps 1 and 2 above.

B. Enter the new values.

C. Touch and hold the procedure name for more than 2 seconds; you will hear a beeping sound confirming the settings are saved.

**NOTE:** 300µm tips are recommended for removing thin tissue layers. 400µm tips are recommended for removing fibrous tissue.

## 7.5 TABLE OF PRE-PROGRAMMED SURGICAL SETTINGS

| Setting | | Procedure Name | Power (W) | Pulse Length (Mode) | Pulse Length | Fiber (Tip) Size (µm) | Tip Initiation | Spot Size $(mm)^2$ |
|---|---|---|---|---|---|---|---|---|
| 1 | INCISION | Neck dissection; Dermabrasion; Herniorrhaphy; Open DCR; Blepharoplasty; Tracheobronchial malignancy or stricture; Thoracotomy; Release of urethral stricture; Removal of bladder neck obstruction; Lesions of external genitalia; Circumcision | 1.00 W | CW | CW (Continuous) | E4 (400µm) | Yes | 0.126 |
| 2 | EXCISION | Removal of benign lesions from ear; nose and throat; Excision and vaporization of vocal cord nodules and polyps; Incision and excision of carcinoma in-situ; Laryngeal papillomectomy; Meniscectomy; Syovectomy; Excision and vaporization of colorectal carcinoma; Excision of polyps; Excision of neuromas; Excision of periungual and subungual warts; Excision of plantar warts; Excision of keloids; Excision of cutaneous lesions; Appendectomy; Debridement of decubitus ulcer; Excision, vaporization and hemostasis of abdominal tumors; Excision, vaporization and hemostasis of rectal pathology; Pilonidal cystectomy; Parathyroidectomy; Laparoscopic cholecystectomy; Thyroidectomy; Resection of organs; Excision or vaporization of condylomata acuminate; Myomectomy; Ovarian cystectomy; Tumor excision; Benign and malignant pulmonary obstruction; Pulmonary resection; Pericardiectomy; Excision and vaporization of condyloma; Dermatological surgery; Condyloma acuminate; Warts; Small non-malignant skin tumors; Small semi-malignant tumors and basalomas; Bowe; Kaposi sarcoma; Warty leucoplasty; Mixoid cyst | 0.80 W | CW | CW (Continuous) | E4 (400µm) | Yes | 0.126 |
| 3 | VAPORIZATION | Ablation and vaporization of hyperkeratosis; Excision and vaporization of herpes simplex I and II; Hemorrhoidectomy; Vaporization and hemostasis of capillary hemangioma; Vaporization of CIN (cervical intraepithelial neoplasia); Cervical conization; Percutaneous disc decompression (PLDD); Dacryocystorhinostomy transcanalicular; Adhesiolysis; Vaporization of urethral tumors; Vaporization of the prostate to treat benign prostate hyperplasia (BPH); Pyrogenic granuloma, lymphangioma and lymphangiomatosis disease, angiofibromas; Seborrheic keratosis; Acne treatment | 1.00 W | CW | CW (Continuous) | E4 (400µm) | Yes | 0.126 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 4 | COAGULATION | Chondromalacia; Hemostasis of upper and lower GI bleeding; Hemostasis of colonoscopy; Hemostasis of esophageal varices; Dissect and coagulate; Matrixectomy; Hemostasis in conjunction with meningiomas; Coagulation and hemostasis of cardiac tissue; Hemostasis; Coagulation of blebs and bullae; Photocoagulation of vascular & dermatological lesions of the face and extremities; Photocoagulation of telangiectasia, veinulectasia of the legs and face; Treatment of reticular veins and branch varicosities; Telangiectasias; Hemagioma; Port wine stains; Angiokeratoma; Benign epidermal pigment lesions as lentigines; Epidermal nevi; Spider nevi; Ulcers debridement; Papillary varix | 0.50 W | CW | CW (Continuous) | E4 (400µm) | No | 0.126 |
| 5 | CUSTOM 1 | | 0.1 W | CW | CW (Continuous) | E4 (400µm) | YES | 0.126 |
| 6 | CUSTOM 2 | | 0.1 W | CW | CW (Continuous) | E4 (400µm) | YES | 0.126 |
| 7 | CUSTOM 3 | | 0.1 W | CW | CW (Continuous) | E4 (400µm) | NO | 0.126 |
| 8 | CUSTOM 4 | | 0.1 W | CW | CW (Continuous) | E4 (400µm) | NO | 0.126 |
| 9 | QUICK CUT | | 0.1 W | CW | CW (Continuous) | E4 (400µm) | NO | 0.126 |

*Figure 7.8*

## *7.6 PAIN THERAPY*

The EPIC S-Series diode laser is designed to provide near-infrared laser energy to a tissue surface for the purpose of temporary pain relief when applied with the Deep Tissue Handpiece. The pain therapy procedure is the process by which tissue temperature is elevated for the temporary relief of minor pain, the temporary increase in local blood circulation, and the temporary relaxation of muscle, as stated in the Indications for Use.

Affected muscles and/or joints have to be exposed to an adequate level of therapeutic energy over a short period of time to provide effective therapeutic effects. Some patients may require more than one laser application or a series of treatments before significant improvement is reported. Repeat the therapy as necessary and monitor the progress of the patient's condition throughout the treatment.

Refer to the Fitzpatrick Skin Type Scale (Figure 7.9) when performing pain therapy procedures. The diode wavelength has increased absorption in melanin in the skin, causing greater heating of the skin surface of patients with a higher melanin concentration (darker skin types).

Patients with higher melanin content in their skin may feel more discomfort during treatment, which may be alleviated by moving the handpiece, defocusing the energy, or decreasing the power setting.

| Fitzpatrick Skin Type Scale | |
|---|---|
| TYPE I | Highly sensitive, always burns, never tans. Example: Red hair with freckles |
| TYPE II | Very sun-sensitive, burns easily, tans minimally. Example: Fair-skinned, fair-haired Caucasians |
| TYPE III | Sun-sensitive skin, sometimes burns, slowly tans to light brown. Example: Darker Caucasians |
| TYPE IV | Minimally sun-sensitive, burns minimally, always tans to moderate brown. Example: Mediterranean-type Caucasians |
| TYPE V | Sun-insensitive skin, rarely burns, tans well. Example: Some Hispanics, some Blacks |
| TYPE VI | Sun-insensitive, never burns, deeply pigmented. Example: Darker Blacks |

*Figure 7.9*

## *Pre-programmed Pain Therapy Settings*

To access the pre-programmed procedure values:

1. Go to the Procedures menu by pressing the Pain Therapy icon on the Home screen.
2. Press the button associated with the type of condition requiring treatment.

**CAUTION:** Always use clinical judgment when selecting power to ensure optimal clinical results. Observe the clinical effects on the treatment area at all times and adjust settings parameters accordingly.

To store your personal preferred settings for any procedure:

A. Follow steps 1 and 2 above.

B. Enter the new values.

Touch and hold the condition name for more than 2 seconds; you will hear a beeping sound confirming the settings are saved.

**NOTE:** The pain therapy pre-sets installed at the factory are based on clinical recommendations and feedback from experienced laser medical practitioners.

## *7.7 TABLE OF PRE-PROGRAMMED PAIN THERAPY SETTINGS*

| PROCEDURE NAME | MODE | SETTING | TIME | ENERGY (J) | SPACER |
|---|---|---|---|---|---|
| JOINT PAIN | CW (Continuous) | 4W | 600 seconds | 2400 | 30mm |
| MUSCLE PAIN | CW (Continuous) | 4W | 300 seconds | 1200 | 30mm |
| MUSCLE SPASM | CW (Continuous) | 4W | 300 seconds | 1200 | 30mm |
| CUSTOM | CW (Continuous) | 4W | 60 seconds | 240 | 30mm |

*Figure 7.10*

### *Pain Therapy – Adverse Effects*

Some reddening of the skin at the treatment site is normal due to increased circulation; however, in very rare cases burning or blistering of the skin may occur. **Immediately stop treatment**, rinse the area with cool water or place a cold pack to the affected area for at least 5 minutes, then apply a burn ointment or spray. **DO NOT USE ICE.**

Patients should be monitored for discomfort and visual skin changes. Redness has been associated with increased temperature at the site of application and increased absorption properties of the skin. If discomfort or redness of the skin occurs at any time during the treatment, you have the following options:

- Move the handpiece relative to the affected anatomy
- Defocus the energy by moving the handpiece further away from the skin
- Decrease the power setting
- Stop treatment

### *Pain Therapy – Warnings and Precautions*

- Scar tissue has been associated with poor circulation and reduced cooling through heat transport by blood; power settings may have to be reduced to avoid overheating.
- Patients with tender or sensitive skin may be hypersensitive to heat; reduce power as necessary to ensure comfort during treatment.
- Patients with swelling and/or inflammation may be sensitive to heat; reduce power as necessary to ensure comfort during treatment.
- Do not treat open wounds.
- Muscle tissue closer to the skin surface may experience a higher absorption of heat; carefully monitor skin temperature and reduce power as necessary.
- Excessive fatty tissue is known to transmit heat without much attenuation; reduce power.
- Different implant materials will respond differently to laser energy and heat; be aware of any implants and their location; avoid direct exposure to laser energy or heat at the site of the implant.
- Avoid treatment of sites that have tattoos.
- Do not apply ointment, creams, lotions or heating lotion patches at, or in close proximity to, the treatment area.
- Do not apply therapies prior to treatment that could change body temperature, such as ultrasound, ice/heat pack, electrical stimulation, or heating patches.
- Do not apply treatment over articles of clothing.

### *Recommended Use*

There are four main variables that impact the safety and effectiveness of pain therapy procedures:

- Power output
- Distance from the skin surface
- Range of movement of the handpiece
- Patient skin type

Safety and effectiveness are described by elevating the skin temperature in the treatment area utilizing the settings recommended below. Use personal clinical judgment with consideration of the Fitzpatrick Skin Type Scale when selecting procedure parameters; monitor the patient and adjust the settings as necessary for effectiveness and patient comfort.

| | |
|---|---|
| **NOTE:** | To avoid potential patient discomfort and/or skin damage, it is advisable to use a test spot prior to the initial treatment to assess the suitability of the selected settings for the individual patient. |

## *Using the Deep Tissue Handpiece*

If holding the Handpiece in a constant location, set the screen to the recommended initial power settings for therapeutic effect, 4.0W delivered over 10 minutes (600 seconds) of continuous treatment (CW), with the spacer set at a 30mm spot size. Always monitor patient response; adjust power and/or distance as needed for patient comfort.

# 8. MAINTENANCE

**WARNING:** No modification of this equipment is allowed.

## 8.1 DAILY MAINTENANCE

Use the peel-off clear covers for the laser console supplied with the system. Use disinfectant to wipe down the front panel and handpiece holder of the EPIC S-Series system after each procedure. **Do not use bleach or abrasive cleansers.**

## 8.2 CLEANING AND STERILIZATION PROCEDURES

The contamination control suggested for the EPIC S-Series Surgical Handpiece and tips is the steam sterilization method. However, before sterilization, the EPIC S-Series reusable handpiece should be carefully cleaned per the following procedure.

**CAUTION:**

Handpiece and tips must be sterilized prior to initial use.

**Tips are single-use only** to avoid cross-contamination and are designed to withstand a single sterilization cycle; they must be disposed of after use in a biohazard medical waste Sharps container.

Handpieces are reusable and must be cleaned and sterilized between patients to avoid cross-contamination.

### *Cleaning and Disinfecting Instructions - Surgical Handpiece, Reusable Fiber Optic Cable*

The cleaning process is intended to remove blood, protein and other potential contaminants from the surfaces and crevices of reusable accessories. This process may also reduce the quantity of particles, microorganisms and pathogens present. Cleaning should be performed prior to sterilization and must be conducted only by qualified office personnel trained to perform the procedure and handle the EPIC S-Series fiber optic delivery system.

Wear protective latex gloves when handling the contaminated delivery system.

To disinfect the fiber cable, wipe the entire cable, including the shaft, with an appropriate disinfecting solution, such as Cavicide™ or a similar quaternary ammonium compound product (containing 20% alcohol or less), and follow the manufacturer's instructions. Avoid getting any liquid or debris near the distal end of the fiber cable.

## *Manual Cleaning of the Surgical Handpiece:*

**Cleaning must be performed within a maximum of 1 hour after the procedure and always prior to sterilization.**

1. After use, carefully remove the tip from the handpiece and dispose of in a biohazard medical waste Sharps container.
2. Carefully remove the handpiece from the fiber optic cable (see Section 2).
3. Prepare any commercially available surgical instrument detergent/enzymatic cleaning solution with a pH of 7.0, such as Enzol® or similar enzymatic presoak and cleaner, per the manufacturer's instructions. (Follow the manufacturer's instructions for disposal of used solution.)
4. Rinse the Handpiece under running lukewarm tap water (22 – 43°C) for a minimum of 10 seconds to remove gross soil.
5. Wrap the handpiece in a piece of gauze that has been soaked in the cleaning solution; leave it wrapped in the gauze for a **minimum of 10 minutes**.
6. Unwrap the handpiece from the gauze and use a soft-bristled brush dipped in the cleaning solution to gently scrub it for **at least 15 seconds**.
7. Rinse the handpiece under running lukewarm tap water (22-43°C) for a minimum of 10 seconds and then dry with a lint-free cloth.
8. Visually inspect the handpiece for any residual soil. If necessary, repeat steps 5 - 7 until **all** residual soil is removed.

## *Steam Sterilization for Surgical Handpiece and Single Use Tips*

The steam sterilization process is intended to destroy infectious microorganisms and pathogens.

**NOTE:** Always perform the procedure immediately *after* cleaning and *prior* to use and **only** use CE-marked sterilization accessories, i.e., sterilization pouch and autoclave tray.

- Place the handpiece and fiber tips in separate single-wrap, self-seal autoclave pouches.
- Place on an autoclave tray; do not stack other instruments on top of the pouches.
- Place the tray inside the autoclave chamber and set the appropriate cycle as recommended in Figure 8.1.

| Type of Sterilizer | Temperature | Time (minimum) | Drying Time |
|---|---|---|---|
| Gravity Displacement | 121°C | 30 minutes | 15 – 30 minutes |
| | 132°C | 15 minutes | |
| Dynamic-Air-Removal (Pre-Vacuum) | 132°C | 4 minutes | 20 - 30 minutes |
| | 134°C | | |

*Figure 8.1*

- Once the cycle is completed, remove the tray and let each sterilized item cool and dry. **The handpiece and tips must remain in the sterilization pouches until used in order to maintain sterility.**
- For instructions on how to reassemble the handpiece, please refer to Section 2.7.

## *Disinfecting the Deep Tissue Handpiece*

The Deep Tissue Handpiece is sold with non-sterile, disposable protective shields.

**The handpiece and clear protective shield are not autoclavable.** The clear protective shields are intended for single-time use only and should never be reused.

To disinfect the Deep Tissue Handpiece, wipe the entire outer surface of the handpiece with cotton gauze and isopropyl alcohol.

Always wipe the disposable shield with alcohol prior to use. Dispose of after one-time use.

## 8.3 INSTALLING/REPLACING THE CONSOLE BATTERY PACK

1. To install or replace the battery pack, remove the battery cover on the underside of the console using the Phillips screwdriver included with the laser system (Figure 8.2).
2. To remove the battery, grip the battery at the top and pull the cable away from the connector (Figure 8.3). Do not tug or wrench the cable from the connector.
3. To install the battery, insert the connector wire from the battery to the unit, making sure the red wire is on the left, and gently place the battery into the compartment (Figure 8.3).
4. Replace the battery cover on the bottom of the unit, using a standard Phillips screwdriver.
5. Connect the power cord of the DC power supply to the unit and plug into a wall outlet. Before first use, you should fully charge the battery (at least three (3) hours). Once the battery is charged, unplug the power cord from the wall outlet and the console. The unit will run on battery power alone. (see Section 4.1)
6. Recycle the used Lithium Ion battery as regulated. Do not throw it in a trashbin.

*Figure 8.2: Battery Cover/Bottom of Console*

*Figure 8.3: Battery Pack/Connector Wire*

**NOTE:** Only use the battery pack supplied by BIOLASE. The battery pack is a separate accessory (BIOLASE p/n 6400457).

## 8.4 CHANGING THE WIRELESS FOOTSWITCH BATTERIES

The wireless footswitch is powered by two AAA batteries. When the batteries are low, a warning message will appear on the touchscreen indicating that the batteries need to be replaced. To replace the batteries, unscrew the battery cover on the underside of the

footswitch (Section 3), remove the old batteries, and install the new ones, replacing the cover when done. Dispose of the used batteries as regulated; do not throw them in a trash bin.

Do not press/push/touch the Pairing Button (Figure 8.4) while changing the batteries, as this will disrupt the pairing of the laser console and footswitch.

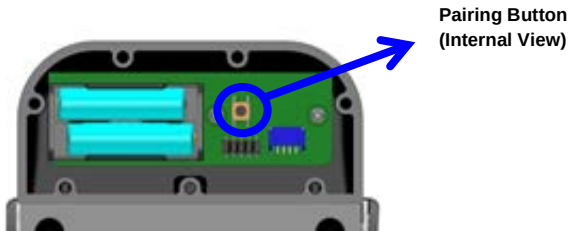



*Figure 8.4*

Replacing the batteries may disrupt the pairing of the laser console and footswitch. If you find the wireless communication has been interrupted, reestablish pairing by following the instructions provided in Section 4.

**NOTE:** To ensure the longevity of the battery power, only BIOLASE-supplied batteries are recommended as replacements (BIOLASE p/n 6400463); these are industrial-grade batteries which under normal use have a longer life than conventional AAA batteries.

## 8.5 TRANSPORTATION

The EPIC S-Series is susceptible to damage if not handled properly. The unit should ALWAYS be handled carefully and never banged, jarred, jolted, dropped, or knocked.

Do not transport the unit unless it is completely packaged inside its shipping box. If you have any questions regarding transportation please call your BIOLASE authorized service representative.

## 8.6 STORAGE

The EPIC S-Series should be stored in a cool, dry place when not in use. Storage temperature 15°C-35°C, relative humidity 10%-70%, non-condensing. Cover the unit when not in use for extended periods of time. Store the system in a place where it will not be accidentally bumped or banged.

**CAUTION:**

Make sure the distal end of the handpiece shaft is protected from dirt with the protective tip plug and handpiece.

Remove the batteries from the footswitch if the EPIC S-Series is not likely to be used for some time.

The EPIC S-Series is shipped inside a custom shipping box. Please save and store the box in a cool, dry place for use when transporting the laser, or for long-term storage.

# 9. CALIBRATION

## 9.1 CALIBRATION SCHEDULE

Calibration procedure is recommended to be performed every twenty-four (24) months in order to maintain the required accuracy of output power versus displayed power. Bi-annual calibrations can be performed at a certified depot repair facility. Call your authorized service representative to schedule an appointment.

# 10. SOFTWARE SPECIFICATION

BIOLASE respects the intellectual property of others, and we ask our users to do the same. EPIC S-Series software is protected by copyright and other intellectual property laws.

This product contains proprietary, copyrighted software developed by BIOLASE, Inc. All rights reserved in the USA and other countries.

# 11. TROUBLESHOOTING

Should any of the on-screen messages listed in Figures 11.1 and 11.2 appear, follow the troubleshooting instructions for the specific message as noted below.

**NOTE:** For any on-screen message not listed in Figures 11.1 and 11.2, re-power the laser console; if the message does not clear, call your authorized service representative

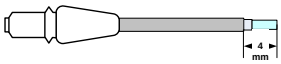
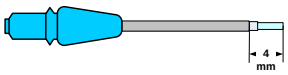
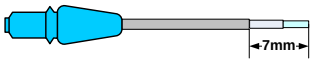
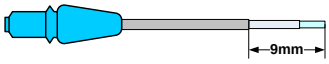
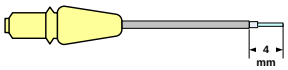
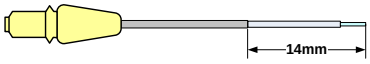
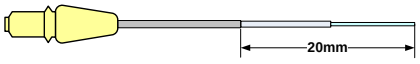
| SCREEN | MESSAGE ! | REASON ? | FIX ✓ |
|---|---|---|---|
| Error 1 | THERMISTOR OPEN | THERMISTOR OPEN | CALL BIOLASE SERVICE |
| Error 2 | THERMISTOR SHORTED | THERMISTOR SHORTED | |
| Error 3 | SHUTDOWN TEMPERATURE | SYSTEM TOO HOT | ALLOW 5-10 MINUTES FOR LASER TO COOL DOWN |
| Error 4 | LASER CURRENT HIGH/LOW | OUTPUT IS OUT OF SPECS | CALL BIOLASE SERVICE |
| ERROR 5 | FOOTSWITCH SHORTED | FS IS PARTIALLY PRESSED OR DAMAGED | PRESS/RELEASE FOOTSWITCH OR CALL BIOLASE SERVICE |
| ERROR 6 | ON/OFF BUTTON STUCK | KEY STUCK | PRESS FRONT KEY |
| ERROR 7 | FLASH CORRUPTED | MEMORY CORRUPTED | CALL BIOLASE SERVICE |
| ERROR 8 | NO FIBER | FIBER NOT INSERTED | PLUG IN TRUNK FIBER |
| ERROR 9 | LOST FOOTSWITCH COMMUNICATION | WIRELESS INTERFERENCE | REPOSITION CONSOLE OR FOOTSWITCH TO IMPROVE COMMUNICATION |
| ERROR 10 | EMERGENCY SWITCH | E-SWITCH PRESSED | PRESS E-SWITCH AGAIN |
| ERROR 11 | REMOTE INTERLOCK | REMOTE INTERLOCK OPEN | CHECK REMOTE INTERLOCK CLOSED |
| ERROR 12 | BATTERY CRITICALLY LOW | BATTERY IS CRITICALLY LOW | PLUG IN DC SUPPLY |
| ERROR 13 | INTERNAL ERROR | INTERNAL ERROR OCCURRED | RESTART UNIT |
| ERROR 14 | FOOTSWITCH BATTERY | FOOTSWITCH BATTERY CRITICALLY LOW | REPLACE FOOTSWITCH BATTERY |

*Figure 11.1*

| SCREEN | MESSAGE ! | REASON ? | FIX ✓ |
|---|---|---|---|
| WARNING 1 | TEMPERATURE HIGH | SYSTEM IS HOT | ALLOW 5-10 MINUTES FOR LASER TO COOL DOWN |
| WARNING 2 | BATTERY IS LOW | BATTERY IS LOW | PLUG IN DC SUPPLY |
| WARNING 3 | BATTERY NOT CONNECTED | BATTERY NOT CONNECTED | PLUG IN THE BATTERY |
| WARNING 4 | FOOTSWITCH BATTERY IS LOW | BATTERY ON THE FOOTSWITCH IS LOW | REPLACE FOOTSWITCH BATTERY |
| WARNING 5 | FOOTSWITCH | FOOTSWITCH HELD | RELEASE FOOTSWITCH |
| ALERT 1 | WIRELESS NOT PAIRED | NO WIRELESS CONNECTION | RE-ESTABLISH PAIRING (SEE SEC 4) |
| ALERT 2 | SYSTEM MUST BE IN READY MODE TO LASE | SYSTEM IS NOT IN READY MODE | PRESS THE CONTROL BUTTON IN ANY PROCEDURE SCREEN |

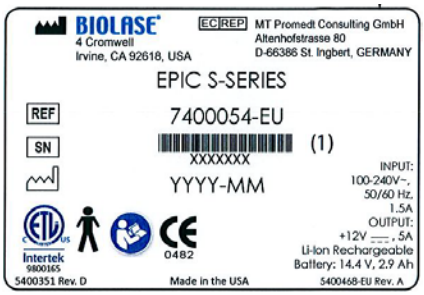
*Figure 11.2*

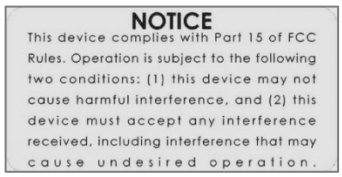
# APPENDIX A – TIP GUIDE

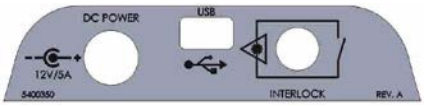
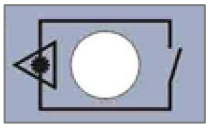
| Tip | Name | Diameter (µm) | Length (mm) | Qty | Part Number |
|---|---|---|---|---|---|
|  | E4-4 | 400µm | 4 | 30 | 7400016 |
| | E4-7 | 400µm | 7 | 15 | 7400019<br>Combo Pack<br>15 x E4-7, 15 x E4-9 |
| | E4-9 | 400µm | 9 | 15 | |
|  | E3-4 | 300µm | 4 | 30 | 7400017 |
|  | E3-7 | 300µm | 7 | 15 | 7400020<br>Combo Pack<br>15 x E3-7, 15 x E3-9 |
|  | E3-9 | 300µm | 9 | 15 | |
|  | E2-4 | 200µm | 4 | 30 | 7400018 |
|  | E2-14 | 200µm | 14 | 30 | 7400021 |
|  | E2-20 | 200µm | 20 | 20 | 7400015 |

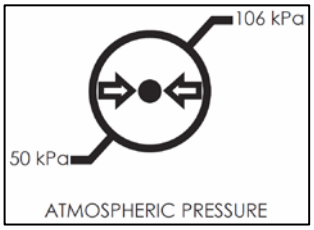
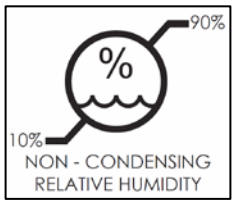
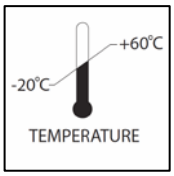
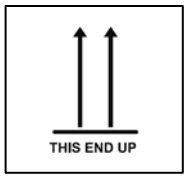
**NOTE:** **All Biolase tips for diode lasers are sold non-sterile and are for single-use only. See Section 8.2 for sterilization instructions.**

# APPENDIX B – LABELING

| Symbols | Description |
|---|---|
|  | **Product ID Label**<br><br>**Location:** Bottom of laser console |
| | **Manufacturer** |
| | **Date of Manufacture** |
| | **Catalog/Part Number** |
| | **Product Serial Number** |
| | **Refer to User Manual** |
| | **Type B Applied Part:**<br>The applied part is not conductive to the patient. |
| | **FDA Compliance Label:**<br>Indicates the device complies with FDA laser standards. |

| | |
|---|---|
| | **Warning Label:**<br>Indicates there is the risk of possible exposure to both infrared and visible laser radiation.<br><br>**Location:** Back of laser console |
| | **FCC Label:**<br>Lists Federal Communication Commission registration number.<br><br>**Location:** Bottom of Console |
| | **FCC Label:**<br>Lists Federal Communication Commission registration number.<br><br>**Location:** Bottom of Footswitch |
|  | **FCC Compliance Notice:**<br>The footswitch and laser console comply with Part 15 of FCC Rules regarding unlicensed transmissions.<br><br>**Location:** Bottom of Footswitch |
| **IPX6** | **Ingress Protection Code:**<br>The footswitch is water-resistant, protected against splashes of water. |
| | **Laser Warning:**<br>Indicates the system contains a laser.<br><br>**Location:** Back of Laser console |
| | **Fiber Warning:**<br>Indicates the laser aperture is at the end of the fiber.<br><br>**Location:** Back of Laser console |

| | |
|---|---|
| | **Emergency Laser Stop Switch:**<br>The switch used in emergencies to stop laser output.<br><br>**Location:** Right side of Laser console |
| | **DO NOT REUSE**<br>**For single use only.** |
| | **WEEE (Waste Electrical and Electronic)**<br>Recycle Lithium Ion battery as regulated. Do not throw in trash bin. |
|  | **DC Power, USB, Remote Interlock Label:**<br>Identifies input ports |
| | **Power Input Rating:**<br>12 Volts Direct Current, 5 amps |
| | **Mini USB Input:**<br>For external programming |
|  | **Remote Interlock:**<br>Input for Remote Interlock Connector which, when applied to the access door of the operatory and activated, will shut off the laser. |

| | |
|---|---|
| Rx Only<br>4400417 Rev A | **Prescription Statement:**<br>Federal Law restricts this device to sale by or on the order of a physician or other licensed medical practitioner. |
|  | **Atmospheric Pressure Limitations** |
| | **Fragile:**<br>Handle with care |
| | **Keep Dry** |
|  | **Humidity Limitations** |
|  | **Temperature Limitations** |
|  | **This End UP** |

# APPENDIX C – SAFETY PRECAUTIONS FOR LITHIUM-ION BATTERY PACKS

***When USING the BATTERY***

**WARNING**

1. Misusing the battery may cause the battery to get hot, rupture, or ignite and cause serious injury. Be sure to follow the safety rules listed below:

    - Do not place the battery in fire or heat the battery.
    - Do not install the battery backwards so that the polarity is reversed.
    - Do not connect the positive terminal and the negative terminal of the battery to each other with any metal object (such as a wire).
    - Do not carry or store the batteries together with necklaces, hairpins, or other metal objects.
    - Do not pierce the battery with nails, strike the battery with a hammer, step on the battery, or otherwise subject it to strong impacts or shocks.
    - Do not solder directly onto the battery.
    - Do not expose the battery to water or salt water, or allow the battery to get wet.

2. Do not disassemble or modify the battery. The battery contains safety and protection devices which, if damaged, may cause the battery to generate heat, rupture, or ignite.
3. Do not place the battery on or near fires, stoves, or other high-temperature locations. Do not place the battery in direct sunshine or use or store the battery inside cards in hot weather. Doing so may cause the battery to generate heat, rupture, or ignite. Using the battery in this manner may also result in a loss of performance and a shortened life expectancy.

**CAUTION**

1. If the device is to be used by small children, the caregiver should explain the contents of the user's manual to the children. The caregiver should provide adequate supervision to ensure that the device is being used as explained in the user's manual.
2. When the battery is worn out, insulate the terminals with adhesive tape or similar materials before disposal.
3. Immediately discontinue use of the battery if, while using, charging, or storing the battery, the battery emits an unusual smell, feels hot, changes color, changes shape, or

appears abnormal in any other way. Contact your sales location or BIOLASE if any of these problems are observed.

4. Do not place the batteries in microwave ovens, high-pressure containers, or on induction cookware.
5. In the event that the battery leaks and the fluid gets into one's eye(s), do not rub the eye(s). Rinse well with water and immediately seek medical care. If left untreated, the battery fluid could cause damage to the eye.

### *When CHARGING the Battery*

**WARNING**

1. Be sure to follow the rules listed below while charging the battery. Failure to do so may cause the battery to become hot, rupture, or ignite and cause serious injury.
   - When charging the battery, either use a specified battery charger or otherwise ensure that the battery charging conditions specified are met.
   - Do not attach the batteries to a power supply plug or directly to a car's cigarette lighter.
   - Do not place the batteries in or near fire, or into direct sunlight. When the battery becomes hot, the built-in safety equipment is activated, preventing the battery from charging further, and heating the battery can destroy the safety equipment and can cause additional heating, breaking, or ignition of the battery.
2. Do not continue charging the battery if it does not recharge within the specified charging time. Doing so may cause the battery to become hot, rupture, or ignite.

**CAUTION**

The temperature range over which the battery can be charged is 0°C to 45°C. Changing the battery at temperatures outside of this range may cause the battery to become hot or to break. Charging the battery outside of this temperature range may also harm the performance of the battery or reduce the battery's life expectancy.

### *When DISCHARGING the Battery*

**WARNING**

Do not discharge the battery using any device except for the specified device. When the battery is used in devices aside from the specified device it may damage the performance of the battery or reduce its life expectancy, and if the device causes an abnormal current to flow, it may cause the battery to become hot, rupture, or ignite and cause serious injury.

**CAUTION**

The temperature range over which the battery can be discharged is -20°C to 60°C. Use of the battery outside of this temperature range may damage the performance of the battery or may reduce its life expectancy.

# APPENDIX D - SPARE PARTS & ACCESSORIES

| BIOLASE p/n | Description |
|---|---|
| 6400479 | Surgical Handpiece (2-pack) |
| 2400040 | Laser Safety Glasses (Clinician) |
| 2400078 | Laser Safety Glasses (Patient) |
| 6400058 | Remote Interlock Plug |
| 2400129 | Power Cord with Power Supply |
| 6400516 | Wireless Footswitch |
| 6400107 | Tip Initiation Kit |
| 6400311 | Deep-Tissue Handpiece |
| 6400310 | Deep-Tissue Handpiece protective covers (qty. 20) |
| 6400465 | Peel-off clear screen covers (qty. 30) |
| 6400457 | Lithium ion battery pack for console |
| 6400463 | Battery Pack, (2 x AAA) |
| 6400437 | Trunk Fiber Assembly |

# APPENDIX E – ELECTROMAGNETIC COMPATIBILITY

| | |
|---|---|
| **CAUTION:** | Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the following tables.<br><br>Portable and mobile Radio Frequency (RF) communications equipment can affect medical electrical equipment. |

Accessories: Medical grade power cord, maximum length 3ft (1 meter), Biolase p/n 2400043.

Footswitch: Wireless, Biolase p/n 6400516

| | |
|---|---|
| **WARNING:** | The use of accessories, other than those specified, except those supplied or sold by Biolase, Inc. as replacement parts for internal or external components, may result in increased EMMISSIONS or decreased IMMUNITY of the EPIC diode laser system. |

| **GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS** | | |
|---|---|---|
| The Epic diode laser is intended for use in the electromagnetic environment specified below. The customer or the user of the Epic diode laser should assure it is used in such an environment. | | |
| **Emissions Test** | **Compliance** | **Electromagnetic environment - guidance** |
| RF emissions<br><br>CISPR 11 | **Group 1** | The Epic diode laser uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions<br><br>CISPR 11 | **Class A** | The Epic diode laser is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions<br><br>IEC 61000-3-2 | **Class A** | |
| Voltage fluctuations/flicker emissions<br><br>IEC 61000-3-3 | **Class A** | |

| GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY | | | |
|---|---|---|---|
| The Epic diode laser is intended for use in the electromagnetic environment specified below. The customer or the user of the model Epic diode laser should assure that it is used in such an environment. | | | |
| **Immunity test** | **IEC 60601 test level** | **Continuous level** | **Electromagnetic environment - guidance** |
| Electrostatic discharge (ESD)<br><br>IEC 61000-4-2 | ± 6 kV contact<br><br>± 8kV air | ± 6 kV contact<br><br>± 8kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, relative humidity should be at least 50%. |
| Electrical fast transient/burst<br><br>IEC61000-4-4 | ± 2 kV for power supply lines<br><br>± 1 kV for input/output lines | ± 2 kV for power supply lines<br><br>N/A | Main power quality should be that of a typical commercial or hospital environment.<br><br>N/A |
| Surge<br><br>IEC 61000-4-5 | ± 1 kV differential mode<br><br>± 2 kV common mode | ± 1 kV differential mode<br><br>± 2 kV common mode | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines.<br><br>IEC 61000-4-11 | <5% $U_r$ (>95% dip in UT) for 0.5 cycle<br>40% $U_r$ (60% dip in UT) for 5 cycles<br>70% $U_r$ (30% dip in $U_r$) for 25 cycles<br><5% Ur (>95% dip in $U_r$) for 5 seconds | <5% $U_r$ (>95% dip in UT) for 0.5 cycle<br>40% $U_r$ (60% dip in UT) for 5 cycles<br>70% $U_r$ (30% dip in $U_r$) for 25 cycles<br><5% Ur (>95% dip in $U_r$) for 5 seconds | Mains power quality should be that of a typical commercial or hospital environment. If the user of the model Epic diode laser requires continued operation during power mains interruptions, it is recommended that the model Epic diode laser be powered from an uninterrupted power supply. |
| Power frequency (50-60 Hz) magnetic field<br><br>IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |

NOTE: $U_r$ is the A.C. mains voltage prior to applications of the test level.

**GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY *(Continued)***

The model Epic laser is intended for use in the electromagnetic environment specified below. The customer or the user of the model Epic laser should assure that it is used in such an environment.

| Immunity test | IEC 60601 test level | Continuous level | Electromagnetic environment - guidance |
|---|---|---|---|
| Conducted RF<br>IEC 61000-4-6<br><br>Radiated RF<br>IEC61000-4-3 | 3 Vrms<br>150 kHz to 80 GHz<br><br>3V/m<br>80 MHz to 2.5 GHz | 3 V<br><br>3Vm | Portable and mobile RF communications equipment should be used no closer to any part of the model Epic diode laser, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>**Recommended separation distance**<br>d = 1.2√P<br>d = 1.2√P 80 MHz to 800 MHz<br>d = 2.3√P 800MHz to 2.5GHZ<br>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d 8s the recommended separation distance in meters (m).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]<br>Interference may occur in the vicinity of equipment marked with the following symbol: |

**NOTE 1** - At 80 MHz and 800 MHz, the higher frequency range applies.

**NOTE 2** – These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

A. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephone and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Epic diode laser is used exceeds the applicable RF compliance level above, the Epic diode laser should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Epic diode laser.
B. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

**RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE EPIC DIODE LASER**

The Epic diode laser is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Epic diode laser can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Epic diode laser as recommended below, according to the maximum output power of the communications equipment.

| **Rated maximum output power of transmitter W** | **Separation distance according to frequency of transmitter M** | | |
|---|---|---|---|
| | 150kHz to 80Mhz<br>$d = 1.2\sqrt{P}$ | 80 MHz to 800 MHz<br>$d = 1.2\sqrt{P}$ | 800 MHz to 2.5 GHz<br>$d = 2.3\sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

**NOTE 1** – At 80 MHz and 800 MHZ, the separation distance for the higher frequency range applies.

**NOTE 2** – These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

# APPENDIX F - WIRELESS EQUIPMENT COMPLIANCE STATEMENT

This statement applies only to the wireless portion of the device:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

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Conforms to:
AAMI ES60601-1
IEC60601-1
IEC6060-2-22
IEC62366
IEC80601-2-60
IEC60825-1
Certified to:
CSA C22-2 No. 60601-1

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# About BIOLASE

Founded in 1986, BIOLASE, Inc. specializes in lasers for medicine and dentistry that feature proprietary and patented technologies for performing minimally invasive surgeries, reducing pain and improving clinical results.

Only BIOLASE combines the leading laser technology – continuously improved through ongoing clinical R&D and engineering – with unmatched training, practice integration support and service.

**Made in the USA. Rx Only.**

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